



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,128	11/03/2000	Xiaoling Xie	VP198-04 CON	7839

7590

02/10/2004

Fish & Neave
1251 Avenue of the Americas
New York, NY 10020

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 02/10/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,128

Applicant(s)

XIE ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 7 and 8.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group V, claims 16-18, in Paper No. 13, filed September 18, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 16-18 are examined on the merits.

Specification

4. The title of the invention is not descriptive because the instant title is directed to a composition, "Crystallizable JNK Complexes," while the elected invention is directed to a method. A new title is required that is clearly indicative of the invention to which the claims are directed.

Sequence Compliance

5. The amendment to the sequence listing does not comply with the sequence rules as required under 37 CFR § 1.821(f). Applicant has not included in the paper, filed December 18, 2003, which accompanied the new sequence listing, a statement that the "Sequence Listing" content of the paper or compact disc copy and the computer readable copy are the same must be submitted with the computer readable form, e.g., a statement that "the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing." Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement

Art Unit: 1631

may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

OBJECTIONS

6. Applicants' amendment to replace the paragraph beginning on page 43, line 16, which starts with "Figures 1a-5" in the instant Specification, Paper 13, filed September 18, 2003, is objected to due to the insertion of "Figures 1B-5" wherein said figures do not exist.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Specific to claims 16, 18, line 2; and 17, last line, Applicant uses the abbreviations of "JNK3". Abbreviations in claims are vague and indefinite unless accompanied by the full name, usually in parentheses.

10. Specific to claims 16, 17, line 8; and 18, line 3, the recitation of Figure 1 causes the claim to be vague and indefinite due to said figure is no longer in the drawings.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1631

12. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal structure of JNK3 α 1, does not reasonably provide enablement for any molecule comprising a JNK3-like binding pocket. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

13. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

14. It is acknowledged that the applicant has disclosed information to enable one skilled in the art to make a specific crystal of the JNK α 1 for practicing the claimed invention Examples 1-6. However, a method that relies on data from an unpredictable art such as protein crystallization would require clear and precise guidance for one skilled in the art to reliably use the said method. It is well documented that protein crystallization is in essence a trial-and-error method, and the results are usually unpredictable (Drenth, J.). Further, as recently as November 1, 2002, *Science* published a *New Focus* article depicting the current state of the art for protein

Art Unit: 1631

crystallization that supports the unpredictability of the art. In essence, protein crystallization is still a trial and error process because the current technology for producing protein for the crystallization process is unpredictable, which results in high failure rate for proteins that are being crystallized. Therefore, researchers continue to have trouble generating sufficient protein required for the crystallization process (New Focus, Science, 2002). Accordingly, it would be unpredictable for one skilled in the art to make crystal structures of other molecules beyond the ones of the instant case where specific coordinates are disclosed. In light of the difficulty of the protein crystallization process, it is, therefore, unreasonable to expect one skilled in the art to use the information disclosed for one specific crystal to make other of predictable quality to practice the method of the claimed invention without undue experimentation.

15. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal structure of JNK3 α 1, does not reasonably provide enablement for a method for identifying both an agonist and an antagonist of a molecule comprising a JNK3-like binding pocket. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

16. It is acknowledged that Applicant has disclosed information to enable one skilled in the art to make a specific crystal of the JNK α 1 for practicing the claimed invention as directed to the identification of inhibitors Examples 5 and 6. However, the instant specification does not enable one of skill in the art to practice the claimed invention as directed to identifying both an agonist and an antagonist of a molecule comprising a JNK3-like binding pocket with the same binding

Art Unit: 1631

pocket atomic coordinates. For example, different effectors, agonists or antagonists, have different functions, which are defined by their respective chemical and biochemical properties. These distinct chemical and biochemical properties determine how either agonists or antagonists interact with JNK α 1, therefore, determine their respective mechanisms of action. How are such different effectors with distinct chemical and biochemical properties identified by the same method such as the one in Examples 5 and 6? The lack of guidance provided by the instant specification as to how one of skill in the art to use the claimed method as directed to the identification of either an agonist or antagonist causes to be not enabled commensurate in scope with these claims. Therefore, one skilled in the art would require undue experimentation to predictably practice the claimed invention.

CLAIM REJECTIONS - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1631

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al. (US 6,162,613 A) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

20. Su et al. discloses a method for identifying an inhibitor (agonist or antagonist) of JNK3 (claim 6). The method of Su et al. comprises using X-ray coordinates, contact between JNK3 and inhibitors are determined via modeling and binding assays, and inhibitors such as pyridinyl-imidazoles (SB203580) are identified (Examples 4 and 5) wherein the inhibitor is created (column 4, lines 16-20), as in instant claims 16-18.

21. Even though the method disclosed by Su et al. does not specify that the atomic coordinates of JNK3 according to Figure 1, the specific limitations of atomic coordinates in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

22. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. Also, the MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, atomic coordinates in Figure 1 are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed

Art Unit: 1631

by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

23. Clearly, an artisan of ordinary skill in the art would have been motivated to partake the method emphasized by Su et al. to practice the said for identifying inhibitors of JNK3.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Su et al. for identifying inhibitors of JNK3.

CONCLUSION

24. NO CLAIM IS ALLOWED.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

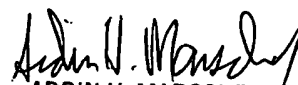
C. Dune Ly

Application/Control Number: 09/706,128

Page 9

Art Unit: 1631

2/5/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER